

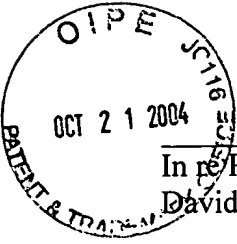
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1654

Express Mail Label No.	Dated: _____
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Docket No.: 01946/100D864-US1
(PATENT)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
David Gschneider et al.

Application No.: 09/762,067

Confirmation No.: 7883

Filed: August 3, 2001

Art Unit: 1654

For: COMPOUNDS AND COMPOSITIONS FOR
DELIVERING ACTIVE AGENTS

Examiner: Maury Audet

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

A copy of each document on the PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as

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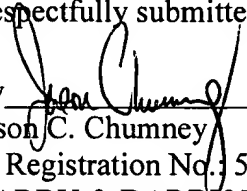
defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

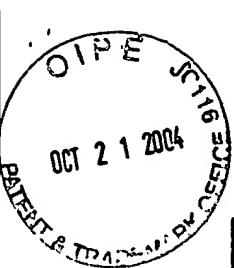
Our check in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p) is enclosed. The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: October 21, 2004

Respectfully submitted,

By 
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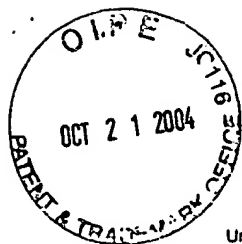


PTO/SB/17 (10-04)
Approved for use through 7/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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FEE TRANSMITTAL for FY 2005 <small>Effective 10/01/2004. Patent fees are subject to annual revision.</small>		Complete if Known																																											
		Application Number	09/762,067																																										
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27		Filing Date	August 3, 2001																																										
		First Named Inventor	David Gschneidner et al.																																										
		Examiner Name	Maury Audet																																										
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METHOD OF PAYMENT (check all that apply)		FEE CALCULATION (continued)																																											
<input checked="" type="checkbox"/> Check <input type="checkbox"/> Credit Card <input type="checkbox"/> Money Order <input type="checkbox"/> Other <input type="checkbox"/> None <input type="checkbox"/> Deposit Account: Deposit Account Number: 04-0100 Deposit Account Name: Darby & Darby P.C. The Director is authorized to: (check all that apply) <input type="checkbox"/> Charge fee(s) indicated below <input checked="" type="checkbox"/> Credit any overpayments <input checked="" type="checkbox"/> Charge any additional fee(s) or any underpayment of fee(s) <input type="checkbox"/> Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.		3. ADDITIONAL FEES																																											
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<table border="1"><thead><tr><th>Fee Code</th><th>Fee (\$)</th><th>Fee Code</th><th>Fee (\$)</th><th>Fee Description</th><th>Fee Paid</th></tr></thead><tbody><tr><td>1001</td><td>790</td><td>2001</td><td>395</td><td>Utility filing fee</td><td></td></tr><tr><td>1002</td><td>350</td><td>2002</td><td>175</td><td>Design filing fee</td><td></td></tr><tr><td>1003</td><td>550</td><td>2003</td><td>275</td><td>Plant filing fee</td><td></td></tr><tr><td>1004</td><td>790</td><td>2004</td><td>395</td><td>Reissue filing fee</td><td></td></tr><tr><td>1005</td><td>160</td><td>2005</td><td>80</td><td>Provisional filing fee</td><td></td></tr><tr><td colspan="4">SUBTOTAL (1)</td><td>(\$)</td><td>0.00</td></tr></tbody></table>		Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid	1001	790	2001	395	Utility filing fee		1002	350	2002	175	Design filing fee		1003	550	2003	275	Plant filing fee		1004	790	2004	395	Reissue filing fee		1005	160	2005	80	Provisional filing fee		SUBTOTAL (1)				(\$)	0.00	251 55 Extension for reply within first month	
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		2403 150 Request for oral hearing																																											
		1451 1,510 Petition to institute a public use proceeding																																											
		1452 110 Petition to revive - unavoidable																																											
		1453 1,370 Petition to revive - unintentional																																											
		1501 1,370 Utility issue fee (or reissue)																																											
		1502 490 Design issue fee																																											
		1503 660 Plant issue fee																																											
		1460 130 Petitions to the Commissioner																																											
		1807 50 Processing fee under 37 CFR 1.17(q)																																											
		1806 180 Submission of Information Disclosure Stmt																																											
		8021 40 Recording each patent assignment per property (times number of properties)																																											
		1809 790 Filing a submission after final rejection (37 CFR 1.129(a))																																											
		1810 790 For each additional invention to be examined (37CFR 1.129(b))																																											
		1801 790 Request for Continued Examination (RCE)																																											
		1802 900 Request for expedited examination of a design application																																											
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SUBMITTED BY		(Complete if applicable)																																											
Name (Print/Type) Jason C. Chumney		Registration No. (Attorney/Agent) 54,781																																											
Signature		Telephone (212) 527-7700																																											
		Date October 21, 2004																																											

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PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	09/762,067	
			Filing Date	August 6, 1999	
			First Named Inventor	David Gschneidner et al.	
			Art Unit	1654	
			Examiner Name	Maury Audet	
Sheet	1	of	3	Attorney Docket Number	01946/100D864-US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Memorandum
		Number-Kind Code ² (if known)			
	1	6,699,467	03/2/2004	Leone-Bay, et al.	
	2	6,693,208	02/17/2004	Gschneidner, et al.	
	3	6,693,073	02/17/2004	Milstein, et al.	
	4	6,663,887	12/16/2003	Leone-Bay, et al.	
	5	6,646,162	11/11/2003	Tang, et al.	
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	7	6,627,228	09/30/2003	Milstein, et al.	
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	9	6,610,329	08/26/2003	Santiago, et al.	
	10	6,525,020	02/25/2003	Leone-Bay, et al.	
	11	6,461,643	10/08/2002	Milstein, et al.	
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	13	6,428,780	08/06/2002	Leone-Bay, et al.	
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	16	6,384,278	05/07/2002	Tang, et al.	
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	18	6,348,207	02/19/2002	Milstein, et al.	Certificate of Correction
	19	6,346,242	02/12/2002	Leone-Bay, et al.	Certificate of Correction
	20	6,344,213	02/05/2002	Leone-Bay, et al.	
	21	6,313,088	11/06/2001	Leone-Bay, et al.	
	22	6,245,359	06/12/2001	Milstein, et al.	Certificate of Correction
	23	6,242,495	06/05/2001	Leone-Bay, et al.	
	24	4,927,928	05/22/1990	Shroot, et al.	
	25	4,900,730	02/13/1990	Miyauchi	
	26	4,835,312	05/30/1989	Itoh, et al.	
	27	US 2002-0001591	01/03/2002	Santiago, et al.	
	28	US 2002-0120009	08/29/2002	Leone-Bay, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	29	WO99/29705	06/17/1999	Glycomed Inc.		
	30	WO98/50341	11/12/1998	Emisphere Technologies, Inc.		
	31	WO98/25589	06/18/1998	Emisphere Technologies, Inc.		
	32	WO97/47270	12/18/1997	Arad, Dorit		
	33	WO97/10197	03/20/1997	Emisphere Technologies, Inc.		
	34	WO95/28838	11/02/1995	Emisphere Technologies, Inc.		
	35	WO95/28920	11/02/1995	Emisphere Technologies, Inc.		

(W:01946/1 00d864us1)	DATE CONSIDERED:
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			Art Unit	1654	
			Examiner Name	Maury Audet	
Sheet	2	of	3	Attorney Docket Number	01946/100D864-US1

36	WO03/057650	07/17/2003	Emisphere Technologies, Inc.		
37	WO03/057170	07/17/2003	Emisphere Technologies, Inc.		
38	WO03/045306	06/05/2003	Emisphere Technologies, Inc.		
39	WO03/026582	04/03/2003	Emisphere Technologies, Inc.		
40	WO02/19969	03/14/2002	Emisphere Technologies, Inc.		
41	WO02/100338	12/19/2002	Emisphere Technologies, Inc.		
42	WO02/070438	09/12/2002	Emisphere Technologies, Inc.		
43	WO02/069937	09/12/2002	Emisphere Technologies, Inc.		
44	WO01/92206	12/06/2001	Emisphere Technologies, Inc.		
45	WO01/70219	09/27/2001	Emisphere Technologies, Inc.		
46	WO01/51454	07/19/2001	Emisphere Technologies, Inc.		
47	WO01/44199	06/21/2001	Emisphere Technologies, Inc.		
48	WO01/32596	05/10/2001	Emisphere Technologies, Inc.		
49	WO01/32130	05/10/2001	Emisphere Technologies, Inc.		
50	WO00/59863	10/12/2000	Emisphere Technologies, Inc.		
51	WO00/59480	10/12/2000	Emisphere Technologies, Inc.		
52	WO00/50386	08/31/2000	Emisphere Technologies, Inc.		
53	WO00/48589	08/24/2000	Emisphere Technologies, Inc.		
54	WO00/46182	08/10/2000	Emisphere Technologies, Inc.		
55	WO00/40203	07/13/2000	Emisphere Technologies, Inc. And Virginia Commonwealth University		
56	WO00/07979	02/17/2000	Emisphere Technologies, Inc.		
57	WO00/06534	02/10/2000	Emisphere Technologies, Inc.		
58	WO00/06184	02/10/2000	Emisphere Technologies, Inc.		
59	JP2239980	09/21/1990	Fuji Film Company, Ltd.		(Abs)
60	FR985.340	11/02/1966	Francia Pharmaceutica		
61	EP576941	06/19/1993	Nisshin Flour Milling Co.		
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63	EP05-17211	09/12/1992	Teikoku Seiyaku Kabushiki		
64	EP00/36145	09/23/1981	Inter, Research Corp.		
65	EP00/07979	05/18/2000	Dynamit Nobel AKtiengesellschaft		

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¹ Applicant's unique citation designation number (optional). ² See attached Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	66	LEONE-BAY, A. "Microsphere Formation in a Series of Derivatized Alpha-Amino Acids: Properties, Molecular Modeling, and Oral Delivery of Salmon Calcitonin"; Journal of Medicinal Chemistry vol 38, 4257-4262 (1995)		
	67	ANDREA LEONE-BAY "4-(4-Salicyloylaminophenyl)butyric Acid as a Novel Oral Delivery Agent for Recombinant Human Growth Hormone" Medi 006, Presented at the American Chemical Society, (March 1996) New Orleans, LA		
	68	HO KOC-KAN; et al. " Solution Phase Preparation of Highly Pure Amide Mixtures Via In-Situ Chlorotrimethylsilane Protection and Activation" Synthetic Communication, vol. 27, no. 5: 883-895 (1997)		

(W:01946/1
00d864us1)

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			Art Unit	1654	
			Examiner Name	Maury Audet	
Sheet	3	of	3	Attorney Docket Number	01946/100D864-US1

69	LEONE-BAY, A. "Synthesis And Evaluation Of Compounds That Facilitate The Gastrointestinal Absorption Of Heparin"; Journal of Medicinal Chemistry vol 41, 1163-1171 (1998)	
70	PICCIOLA G.: "Synthesis Of Quinazolinone And Benzoxazinone Acids And Study Of Their Anti-Inflammatory Properties" IT, Il Farmaco, Ed. Sc. vol 31, no. 9 pgs 655-664 - English Translation (1976)	Abs
71	PICCIOLA G.: "Synthesis Of Quinazolinone And Benzoxazinone Acids And Study Of Their Anti-Inflammatory Properties" Chem Abstract 86:5402t (1977)	
72	PALAGIANO, F., ET AL. "Synthesis, Stability And Anticonvulsant Activity Of Two New GABA Prodrugs" Pharmazie 52(4): 272-276 (1997)	
73	Chem Abstract 73548-12-6	
74	Chem Abstract 70204-54-5 (04/1991)	
75	Johansen, Marianne, et al. "The Kinetics of Decompn. Of Various N-Mannich Bases of Salicylamide" Int. J. Pharm. (1980), 7(2): 119-27 (1980)	
76	Rivera, Theresa M. et al. "Oral Delivery Of Heparin In Combination With Sodium n N-[8-2-Hydroxybenzoyl] Amino)Caprylate: Pharmacological Considerations" Pharmaceutical Research, Vol. 14(12) 1830-1834 (1997)	
77	Andrea Leone-Bay "4-(4-Salicyloylaminophenyl)Butyric Acid as a Novel Oral Delivery Agent For Recombinant Human Growth Hormone" Medi 006, Presented at the American Chemical Society, March 24-28, 1997 New Orleans, LA.	
78	Leone-Bay, A., et al. "The Evolution of an Oral Heparin Dosing Solution" Drugs of the Future Vol. 22(8) 885-891 (1997)	
79	Brayden, D. et al. "Heparin Absorption Across The Intestine: Effects of Sodium N-[8-2-Hydroxybenzoyl] Amino] Caprylate In rat in situ Intestinal Instillations Ind In Caco-2 Monolayers" Pharmaceutical Research Vol 14(2) 1772-1779 (1997)	
80	Leone-Bay, a. "Acylated Non-Alpha-Amino Acids As Novic Agents For The Oral Delivery Of Heparin Sodium, USP" Journal of Controlled Release 50: 41-49 (1998)	
81	Leone-Bay, A. "4-[4-[(2-Hydroxybenzoyl)Amino]Phenyl]Butyric Acid as a Novel Oral Delivery Agent for Recombinant Human Growth Hormone"; Journal of Medicinal Chemistry Vol 39, 2571-2578 (1996)	
82	Leone-Bay, A. "N-Acylated Alpha-Amino Acids As Novel Oral Delivery Agents For Proteins"; Journal of Medicinal Chemistry Vol. 38, 4263-4269 (1995)	
83	Ho Koc-Kan, et al. "A Practical Synthesis Of -Aminoalkanoic Acid Derivatives Form Cycloalkanones" Synthetic Communication, Vol. 26, No. 14:2641-2649 (1996)	
84	Gurrieri and Siracusa: "Thermal Condensation of Some Alpha-Aminoacids With Phthalic Acid" Thermochemica Acta, 7 (1973) 231-239.	
85	Brown, G. and Foubister, A.J. "Receptor Bindin Sites Of Hypoglycemic Sulfonyleureas and Related (Acylamino)Alkyl-[] Benzoic Acids Jmed Chem 27, 79-81 1984	
86	Chem Abstract 70(25) pp 311 (1969)	
87	Chemical Abstract, Vol. 99(23) Abst. No. 191473I (1983)	
88	Emisphere Technologies Poster Presentation, "Oral Delivery of Human Insulin In Diabetic Rats Using Novel Delivery Agents", Monica Carozza, et al. Nov. 16-19, 1998.	
89	Amino Yusuke et al. Chem Pharm Bull 36 pgs. 4426-4434 (1988).	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

(W:\01946\1 00d864us1)	DATE CONSIDERED:
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